

Securing the Preparation Process for Sterile Injectable Anticancer Drugs in a Cytotoxic Safety Cabinet

Introduction & Background

complex process → **risk** management
strict **regulations**

Risques

Related to **patients**, **staff**, the **environment**, or **organizational** matters

Risk

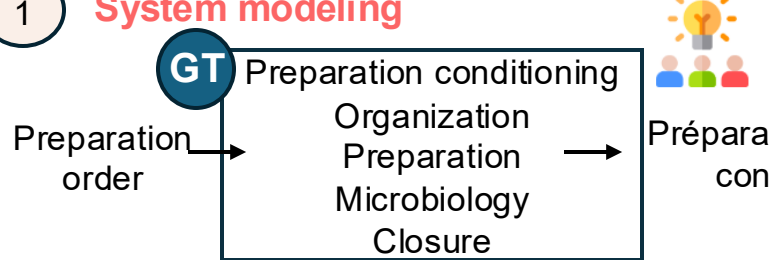
↑ Activity
↑ Variability in training
↑ Staff turn-over
↑ Replacement of sterilizers (isolators)

Critical transition of part of the activity to CSC

Objective:

To develop a risk map using the **Preliminary Risk Analysis (PRA)** method, based on **A. Desroches'** approach, in order to identify **system vulnerabilities** and implement an appropriate **risk management plan**

Matériels & méthodes

- System modeling**

- PRA system**
System ↔ Hazards
Hazardous situations (s/d)
Priorisation index → P1
- PRA scenario**
Initial risks :
 - For each index 1 s/d → 1one or more scenarios (consequences + existing barriers)
 - Initial criticality assessment (Ci)
$$Ci = \text{Initial gravity (Gi)} \times \text{initial plausibility (Vi)}$$

→ Criticality matrix → C2 et C3
- Risk management plan**
 - C2 and C3 → Risk reduction actions → **Prioritized** risk management plan (effort x Ci) and **ranked**
 - Residual risks : **residual Criticality (Cr)**
$$Cr = \text{résidual Gravity (Gr)} \times \text{résidual plausibility (Vr)}$$

(criticality matrix)

Résultats

- Modélisation and PRA système**
 - 31 steps x 30 hazardous elements
 - 276 s/d with an index = 1
- Prioritized action plan**

33 Risk reduction actions including 21 P1

Among the P1 actions :

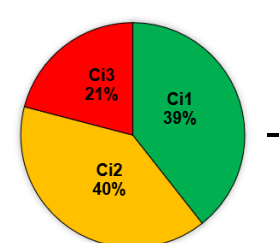
 - 19 prevention actions
 - 2 detection actions

PRA scenarios (hazards/phases)

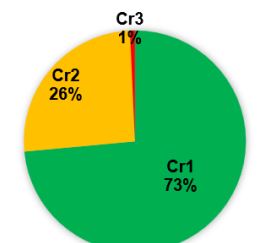
559 scenarios

- 220 C1 (39%) → 408 Cr1 (73%)
- 222 Ci2 (40 %) → 145 Cr2 (26%)
- 117 Ci3 (21 %) → 6 Cr3 (1%)

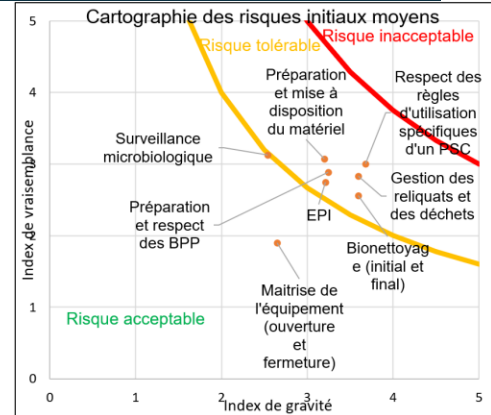
RÉPARTITION DES SCÉNARIIS PAR CRITICITÉ INITIALE



REPARTITION DES SCÉNARIIS PAR CRITICITÉ RÉSIDUELLE

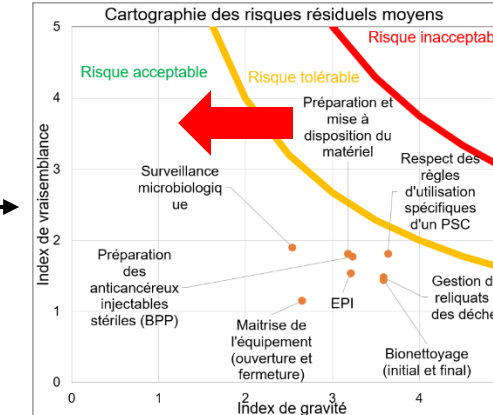


Cartographie des risques initiaux moyens



→

Cartographie des risques résiduels moyens



Grouping the system phases by functional group for analysis

Discussion & conclusion

Risks more closely related to **human**, **organizational**, and **training factors** than to the technical barriers already in place

Limitations: subjectivity of the ratings and comprehensiveness of the scenarios

Outlook: evaluation of the effectiveness of the risk management action plan